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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,320	06/12/2001	Ajay Hasmukhlal Upadhyay	RD 01022	5176

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/879,320	UPADHYAY, AJAY HASMUKHLAL	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-8,31 and 33-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8,31 and 33-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of response dated 7-27-05 is acknowledged.

Claims 1-4, 6-8, 31 and 33-36 are pending in the instant application.

The following rejection of record has been maintained:

Claim Rejections - 35 USC § 103

Claims 1-4, 6-8, 31 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,798,725 to Patel (Patel).

Patel teaches a pharmaceutical composition for oral administration comprising a particulate mixture of an active drug, polyvinylpyrrolidone and a carboxyvinyl polymer (abstract, col. 6, lines 61-68). The particulate mixture of Patel is a flowable and is composed of particles that have a tendency to moderately adhere and yet move (paragraph bridging col. 2-3). Patel teaches PVP in an amount of 5% to 96% (col. 4, lines 10-21), and active agent in an amount of 0.01% to 90% (col. 6, lines 55-60). Patel also teaches that the particles have a size such that they pass through 60 mesh, which accordingly to the instant specification is 250microns and thus is within the claimed range. According to claim 1, <30% of the particles have a size greater than 425 microns and >80% of the particles have a size greater than 45 microns. In other words, the size of the instant particles is between 45 and 425 microns, which includes 250 microns. Example 7 of Patel is directed to a composition of particulate mixture of guaifenesin together with PVP, talc, zinc stearate and Carbopol.

Patel fails to teach the following claim limitations: exact percentages of the particles of specific sizes, agglomerated mixture, percentages of the amounts of

guaifenesin, specific solubilizer maltodextrin and the claimed flow rate. However, Patel teaches a particulate mixture of the same active ingredient and binder as claimed and the particle sizes used by Patel, as explained above, in the same range as claimed. Patel also suggests high amounts of active agent, as high as 90%. Further, the invention of Patel is also directed to a particulate and yet flowable composition (col. 10, lines 37-49), so as to obtain a sustained release of the drug. Furthermore, Patel also suggests addition of the pharmaceutical excipients such as silicon dioxide, stearic acid, talc and other conventional additives (col. 7). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to optimize the amounts of particulate guaifenesin, PVP and other additives, choose the particle sizes and the excipients in the composition of Patel, so as to achieve the desired flow rate of the particle mixture (of active and the excipients) and thus achieve a desired release pattern.

Response to Arguments

Applicant's arguments filed 7-27-05 have been fully considered but they are not persuasive.

Applicants argue that the composition of Patel comprises a capsule shell and particulate mixture of Patel within the shell. It is argued that Patel teaches simply dry blending the ingredients comprising an active drug and PVP. It is argued that PVP is an essential ingredient for sustained release. While agreeing that the particulate mixture of Patel comprises active ingredient, applicants argue that it is only PVP that is present in

a particulate form and not the active ingredient. However, in col. 3, (lines 13-15), Patel clearly states that the active ingredient is in particulate form and hence the argument is moot. Applicants' arguments that PVP of the prior art acts as a sustained release agent and not as a binder is not persuasive because the property to act as a binder is implicit to PVP and applicants have not shown otherwise. Applicants argue that the particle size referred to by the application is only for PVP ad that the preferred embodiment of Patel only teaches 60 mesh. The argument above is not persuasive because, while the prior art teachings are not limited to the preferred embodiments, Patel clearly teaches 250-micron size that is within the claimed particle size. While it is true that Patel does not teach the claimed flow rate, applicants arguments that there is no information in the prior art about flow rate. However, Patel teaches that the compositions should be flowable and accordingly, one of an ordinary skill in the art would be motivated to obtain the desired flowability by adjusting the flow rate of the particulate composition. With respect to the argued distinction of claim 31 i.e., the composition capable of being compressed, the claim requires that the composition of being capable i.e., intended use and does not state that the composition is compressed. Applicants have not shown that the composition of Patel is not capable of being compressed. Therefore, the rejection has been maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lakshmi S Channavajjala
Examiner
Art Unit 1615
October 17, 2005

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600